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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,362	06/17/2000	Gregory Steiner		1986

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/596,362	Applicant(s) STEINER, GREGORY	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 12/23/04.

Information Disclosure Statement

Applicant submitted non-patent literature. However, there is no accompanying Form PTO-1449 listing the submitted references. Applicant may provide a Form PTO-1449 listing the NPL documents provided. Examiner is in receipt of the Coffey et al. article, "Trauma and substance cue reactivity in individuals with comorbid posttraumatic stress disorder and cocaine or alcohol dependence," Drug and Alcohol Dependence, Volume 65, Issue 2, 1 January 2002, pages 115-127.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-6 and 10-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment to the claims.
2. Applicant argues the references together and in light of that approach in applicant's response, the rejections on record will be stated together below.

Claim Rejections - 35 USC § 102

3. Claims 1-3, 6 and 12-16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Cherksey (US 5,234,947).
4. Claims 1, 2 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Umbdenstock (US 5,332,579).

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Claim Rejections - 35 USC § 103

5. Claims 4 and 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cherksey (US 5,234,947).

6. Claims 3-6 and 13-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Umbdenstock (US 5,332,579).

Applicant argues that the organic compounds Cherksey differ from the claimed pyrones because Cherksey discloses substituting the bulky aromatic group of R3 with lower alkyl group and that there are no kavapyrones where lower alkyl group substitutes for the aromatic group that is R3. Applicant further argues that Cherksey's recognition of kawain as a potassium channel activator is not substantiated and that R3 is aromatic in all kavapyrones.

Applicant states that claim 1 is directed to a "new use of known composition of matter" and applicant has not claimed a novel and unobvious property or characteristic that is inherent in a known composition. Applicant argues that the claims are directed to the discovery of a property or characteristic that is inherent to kavapyrones and it is the inherent property or characteristic of the kavapyrones that makes the kavapyrones useful as an anti-craving agent in the treatment of alcoholics. Applicant states that it is the new use and not "the newly discovered property or characteristic, that forms the patentable subject matter of Applicant's independent claim." Applicant states that Cherksey, Umbdenstock and "the other prior art citations" do not describe or appreciate kavapyrones to have "inherent property or characteristic that makes them useful as anti-craving agent in the treatment of alcoholics." Applicants further state that craving is different from withdrawal syndrome in the "science of addiction."

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Applicant's argument primarily centers on Cherksey and since the rejection over Umbdenstock was maintained in the rejection on record, the response to applicant's argument will focus on Cherksey just as applicant's arguments.

7. Applicant's arguments filed 12/23/04 have been fully considered but they are not persuasive.

Although applicant disputes Cherksey's disclosure that kawain is a potassium channel activating substance, applicant does not show that Kawain cannot be a potassium channel-activating agent. The kavapyrones are part of the organic compounds disclosed by Cherksey and disclosed by Cherksey to be effective for treating alcohol or nicotine addiction. Specifically, Cherksey lists kawain, dihydrokawain, methysticin, dihydromethysticin, yangonin and desmethoxyyangonin as examples of the compounds obtained from the Polynesian Kava-kava plant.

When the claim recites using an old composition or **structure** and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). In the present case, the structure is found in kavapyrones and the composition is the formulation that contains the kavapyrones. An individual experiencing withdrawal from alcohol use, craves for the alcohol and thus although, applicant says that withdrawal and craving are not the same, it is clear that alcohol addiction has elements of craving for the alcohol and an addict that has withdrawn from the use also experiences craving and hence the withdrawal effect called syndrome. Addiction/dependence and craving and withdrawal are related. There will be no withdrawal without dependence, there will be no dependence without craving. The American Family Physician article provided by

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applicant recognizes that treatment of withdrawal should be followed by treatment of dependence. The symptoms of the withdrawal applicant refer to appear to overlap the symptoms for craving.

Since applicant does not argue against Umbdenstock, the response to applicant's argument provided in the last office action remains.

No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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